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K001419

510(k) Summary of Safety and Effectiveness for the Solar™ Shoulder Offset Humeral Head

Proprietary Name:	Solar™ Shoulder Offset Humeral Head
Common Name:	Artificial Shoulder Humeral Head
Classification Name and Reference	Shoulder joint humeral (hemi-shoulder) Metallic uncemented prosthesis 21 CFR §888.3690 Or Shoulder Joint metal/polymer semi-constrained Cemented Prosthesis 21 CFR §888.3660
Regulatory Class:	Class II for §888.3690 Class II for §888.3660
Device Product Code:	87 HSD Prosthesis, shoulder, hemi-, humeral, metallic, uncemented 87 KWS Prosthesis, shoulder, semi-constrained, Metal/polymer, cemented
For Information contact:	Karen Ariemma, Regulatory Affairs, Allendale Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 Phone: (201) 760-8187 Fax: (201) 760-8435

The Solar™ Shoulder Offset Humeral Head is a cobalt chromium alloy head that is intended to replace the bearing portion of the humeral head in primary and revision total shoulder arthroplasty. The head is designed to articulate with either the anatomic glenoid or one of the Solar™ Shoulder Glenoid Components (Keeled or Pegged). The subject component will have two bores which can mate with the trunnion of the humeral stem. The center of articulation of the head will be offset radially 4 mm and 8 mm respectively from the Morse taper trunnion locations.

The Solar™ Shoulder Offset Humeral Head is available in outer diameters ranging from 40 to 55 mm in 5 millimeter increments in selected thickness ranging from 15 mm to 28 mm. These heads are manufactured from cast Cobalt Chromium alloy which conforms to ASTM F-75.

The substantial equivalence of the Solar™ Shoulder Offset Humeral Head is based on an equivalence in intended use, materials, and design to the Global Shoulder System – DePuy, Inc., Aequalis™ Shoulder System - Tornier, Inc and the Bigliani/Flatow™ Shoulder System– Zimmer, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2000

Ms. Elizabeth A. Staub
Vice President
Stryker Howmedica Osteonics
59 Route 17
Allendale, New Jersey 07401-1677

Re: K001419
Trade Name: Osteonics® Solar™ Shoulder Offset Humeral Head
Regulatory Class: II
Product Code: HSD and KWS
Dated: May 4, 2000
Received: May 5, 2000

Dear Ms. Staub:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Vochmer

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 001419

Device Name: Osteonics® Solar™ Shoulder Offset Humeral Head

The indications for the use of the Osteonics® Solar™ Shoulder Offset Humeral Head, in keeping with those of other legally marketed Osteonics® Shoulder Components are as follows:

Indications:

- Aseptic necrosis of the humeral head
- Painful, disabling joint disease of the shoulder resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Proximal humeral fracture and/or dislocation
- Revision of previous unsuccessful total shoulder replacement, resurfacing or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochanes

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001419

Prescription Use Yes OR Over-The-Counter Use No

(Per 21 CFR 801.109) (Optional Format 1-2-96)